

### **REMARKS**

The present application relates to methods for detecting a mammalian troponin molecule and for distinguishing between a mammalian troponin molecule and an avian troponin molecule in animal feed. The methods include assays that employ ligands for the detection of mammalian troponin. The Examiner did not enter the amendment filed September 11, 2007, stating that the amendment raised new issues that would require further consideration and/or search. Accordingly, Applicants respectfully request entry of the amendment provided herein. Claims 10-13, 15-17 and 20 are pending. Claims 1-9, 14, 18 and 19 are cancelled. Applicants reserve the right to pursue the subject matter of cancelled claims in a divisional or continuation application. Claim 10 is currently amended. New Claim 20 is added. Support for the amendments is found throughout the specification and original claims, and no new matter is introduced. In light of the following remarks, favorable consideration of the present application is respectfully requested.

#### **Claim rejections under 35 U.S.C. §102(b)**

In the Final Office Action mailed July 11, 2007, and the Advisory Action mailed October 15, 2007, the Examiner rejected Claims 10-16 under 35 U.S.C. §102(b), as anticipated by Sheng *et al.*, (*J. of Bio. Chem.* (1992) vol. 267, pp 25407-25413); hereinafter “Sheng”). Applicants respectfully submit that amendments to the claims overcome the rejection.

Claim 10 has been amended herein to clarify that the method is directed to the detection of mammalian troponin molecules in **animal feed**. Support for this amendment can be found on, at least, page 3, lines 14-16; page 5, lines 6-7. The claimed method teaches the detection of mammalian troponin molecules and that the method also lacks reactivity with avian muscle proteins. It is well known in the art that other assays have been unsuccessful because of their inability to specifically recognize mammalian proteins and exclude avian proteins (see page 3, lines 3-5).

In contrast, Sheng is an article that discusses isolation of a rabbit muscle protein **directly from a rabbit** or from a **bacterial expression system** (see Abstract). The rabbit protein disclosed in Sheng is not isolated, expressed or detected in **animal feed**. Applicants respectfully

submit that “animal feed” is defined in the instant application as “a substance provided to an animal for nourishment” (see page 5, lines 6-7). Applicants respectfully submit Sheng fails to teach or suggest the detection of a mammalian troponin molecule in animal feed. Accordingly, applicants respectfully submit that Sheng fails to teach or suggest the claimed method and respectfully request withdrawal of the rejection.

**Claim rejections under 35 U.S.C. §103(a)**

In the Final Office Action mailed July 11, 2007, and the Advisory Action mailed October 15, 2007, the Examiner rejected Claims 10-18 under 35 U.S.C. §103(a), as being unpatentable over Chen *et al.*, (*Meat Science* (2002) vol. 61, pp. 55-60, available online December 21, 2001); hereinafter “Chen”) in view of Sheng *et al.*, (already of record). Applicants respectfully submit that the amendments to the claims overcome the rejection.

Claim 10 is amended herein to clarify that the ligand is an **antibody produced by immunizing an animal with a peptide having an amino acid sequence selected from the group consisting of SEQ ID NOS: 2-6, 9-13 and 15-35.**

Chen is directed to the development of a thermostable species marker protein for porcine troponin I. Chen states that the development of monoclonal antibodies for the identification of different meats has been hindered, mainly due to limited information on the selection of appropriate antigens (see introduction paragraph). This supports the notion that it was known to one of ordinary skill in the art during December 2001, that production of species-specific monoclonal antibodies **would be ineffective** because the chance of success in selecting a specific clone by screening with crude antigen is **remote** (see Chen introduction paragraph). It is to the applicants' credit that the instant method provides an assay to identify mammalian troponin molecules in **animal feed** through the use of a ligand that **differentiates between mammalian troponin molecules and avian troponin molecules**. Applicants respectfully submit that Chen fails to teach or suggest a ligand that is an antibody produced by immunizing an animal with a peptide having an amino acid sequence selected from the group consisting of **SEQ ID NOS: 2-6, 9-13 and 15-35**. Applicants concur with the Examiner that Chen fails to teach or suggest a ligand that is SEQ ID NO: 2. Accordingly, applicants conclude that the claimed subject matter is not

taught, suggested or provides motivation to one of ordinary skill in the art to derive the claimed subject matter.

Sheng is directed to the isolation and expression of a cDNA for rabbit skeletal muscle troponin I (TnI) from a bacterial expression system or directly from a rabbit. In contrast, the claimed sample is animal feed. Applicants submit that there is no motivation (other than with impermissible hindsight) to apply the cDNA amino acid sequence (Figure 1) of Sheng to an assay that uses **animal feed** to detect mammalian troponin proteins **and that lacks reactivity with avian troponin molecules**.

There is no teaching or suggestion that the cDNA amino acid sequence of Sheng has the **ability to differentiate between mammalian and avian troponin molecules** as claimed herein. Therefore, based on the teachings of Sheng, one of ordinary skill in the art would not conceivably apply the cDNA of Figure 1 to the claimed assay to differentiate between mammalian and avian proteins. Based on the teachings of Chen, unless one of ordinary skill in the art is able to **select an appropriate antigen** (in this instance, one that is reactive with mammalian troponin molecules but lacks reactivity with avian troponin molecules), then testing for a species-specific monoclonal antibody would be predicted to be **ineffective** (see Chen introduction paragraph). Applicants respectfully submit that based on the teachings of the cited references there is no reasonable expectation of success when using the cDNA amino acid sequence of Figure 1 of Sheng other than anticipating a positive reaction for the identification of mammalian troponin. However, there is no teaching or motivation to suggest that the amino acid sequence of Figure 1 is non-reactive with avian troponin molecules as claimed herein.

Furthermore, applicants submit that based on the teachings of Sheng one would expect the cDNA amino acid sequence of Figure 1 to react with other non-mammalian species. Specifically, Sheng teaches that “there is **high level of homology between rabbit, mouse and chicken TnI cDNA's**” (see Figure 2). Additionally, Sheng states that at the nucleotide level, the rabbit sequence is 88% identical to the mouse sequence and 85% identical to the chicken sequence. **At the deduced amino acid sequence level, rabbit TnI is 96% identical to mouse TnI and 93% identical to chicken TnI**” see page 25409, first full paragraph.

Accordingly, applicants respectfully submit that one of ordinary skill in the art would not be motivated to use the cDNA of Sheng as an appropriate antigen to identify a species-specific marker because of the high level of homology between rabbit (mammalian) and chicken (avian) TnI proteins. Accordingly, applicants respectfully submit that it would not be *prima facie* obvious to combine the teachings of Chen and Sheng. Accordingly, applicants respectfully submit they have overcome the rejection under 35 U.S.C. §103(a) and request withdrawal thereof.

**CONCLUSION**

Based upon the amendments and remarks provided above, applicants believe that the pending claims are novel and non-obvious. A Notice of Allowance is therefore respectfully solicited.

No additional fees are believed due; however, the Commissioner is hereby authorized to charge any additional fees that may be required, or credit any overpayment, to Deposit Account No. 11-0855.

If the Examiner believes any informalities remain in the application that may be corrected by Examiner's Amendment, or there are any other issues that can be resolved by telephone interview, a telephone call to the undersigned agent at (404) 815-6473 is respectfully solicited.

Respectfully submitted,

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Attorney Docket No. SDI-0571 (45738-296417)